REMARKS UNDER 37 CFR § 1.116

Formal Matters

Claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-133 are pending after entry of the amendments set forth herein.

Claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-122 were examined and were rejected. No claims were allowed.

New claims 123-133 are added. Support for new claims is found in the presently pending claims and throughout the specification, particularly at: page 5, lines 8-10.

Please replace claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-133 with the clean version provided above.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added by the new claims. Accordingly, their entry by the Examiner is respectfully requested.

Rejection under 35 U.S.C. §§101 and 112, first paragraph

The rejection of claims 77, 79-84, 109-110, and 121 under 35 U.S.C. §§101 and 112, first paragraph, has been maintained. In response to Applicants' arguments filed in response to the original rejection, the Office Action stated:

> Applicant's arguments filed 04 June 2001 have been considered but they are not persuasive. No evidence has been presented that SEQ ID NO:1290 is preferentially expressed in any cancer cell. No utility or enablement for use as a diagnostic agent or

any other utility is thus apparent for the compositions of claims 77, 79-84, and newly filed claims 109, 110, and 121.

The previous Office Action has noted that SEQ ID NOS: 730, 731, 919, 972, 973, 1128, 1254 and 1492 have a disclosed specific utility as a diagnostic since the specification establishes that they are differentially expressed in cancer cells. Applicants also note that, in view of a Declaration under 37 C.F.R. § 1.132 submitted by Applicants showing differential expression of SEQ ID NO: 1192 in colon cancer cells relative to normal colon cells, the Office has withdrawn a similar rejection of claims 77-84.

Applicants have attached a Declaration under 37 C.F.R. § 1.132 by Dr. Randazzo and Dr. Lamson, providing evidence that SEQ ID NO: 1290 represents genes that are differentially expressed in cancer cells (see Exhibit 1). Therefore, it follows that a polynucleotide having a sequence of SEQ ID NO:1290 also has a specific utility as a diagnostic.

In short -- and to summarize in a simplified manner-- the claimed polynucleotides represent genes differentially expressed in cancerous cells and/or represent genes expressed in a cancerous cell (*e.g.*, the polynucleotides were isolated from cDNA libraries of a cancerous cell line, see Example 1). Genes that are expressed in a cancerous cell have utility as, for example, encoding a therapeutic target. Genes that are differentially expressed between cancerous and normal cells have utility in, for example, diagnostics for detection of a cancerous cell.

In view of the specific utility of the sequences, Applicants respectfully request that the rejection of claims 77, 79-84, 109-110, and 121 under 35 U.S.C. § 101 be withdrawn. Moreover, since each of the claimed polynucleotides correspond to a gene that is differentially expressed in cancer cells and have a specific utility as, for example, a diagnostic, one skilled in the art would know how to use the claimed differentially expressed sequences as diagnostics. As such, this rejection of claims 77, 79-84, 109-110, and 121 under 35 U.S.C. § 112, first paragraph, may be withdrawn.

Rejection under 35 U.S.C. §112, first paragraph

The rejection of claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-122 has been maintained for reasons of record in the first Office Action mailed December 1, 2000. In that Office Action, the Office asserted that that the specification provides insufficient written description to support the genus of nucleic acid sequences encompassed by the claims, which include full length cDNA, sequences that hybridize to SEQ ID NOS:730, 731, 919, 972, 973, 1128, 1192, 1254, 1290 and 1492, sequences from other species, mutated sequences, allelic variants, and splice variants. The Office Action further claimed that with the exception of the specific SEQ ID NOS, the skilled artisan cannot

envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. In making the rejection, the Office cited *Amgen, Inc. v. Chugai Pharmaceutical Co.*, *Fiers v. Revel*, *Fiddes v. Baird*, and *University of California v. Eli Lilly and Co.*

In response to Applicants' arguments filed in response to the above-described rejection, the Office states:

> Applicant's arguments filed 04 June 2001 have been fully considered but they are not found persuasive. Notwithstanding the issuance of U.S. Patent No. 5,861,248, the rejection is maintained as being in compliance with the Office guidelines regarding written description. As there is no indication that the claimed SEQ ID NOS contain a complete open reading frame, the use of open language in the claims causes the claimed invention to read on at least a full open reading frame whose sequence is not described in the instant specification.

This rejection is traversed as applied and as it may apply to the presently pending claims.

The presently pending claims are directed to polynucleotides, cDNAs, recombinant host cells, vectors, polynucleotide sequences of inserts contained in ATCC deposited clones, methods of making polypeptides, and cDNAs produced by amplification using a fragment of a specific sequence. The polynucleotide sequences that are the basis for these claims are differentially expressed in cancerous cells relative to normal, non-cancerous cells.

The Office has Not Met Its Burden of Establishing a Prima Facie Case of Lack of Written Description

The inquiry for adequacy of written description is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed. The courts have held that there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed.[1] The Office "has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."[2] With respect to this burden, the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, state:

> A description as filed is **presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.** The examiner, therefore, must have a **reasonable basis** to challenge the adequacy of the written description. The examiner has the **initial burden** of

[1] *See, e.g., In re Wertheim*, 541 F.2d 257 (CCPA 1976).
[2] *Id.* at 263.

presenting by a **preponderance of evidence** why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. In rejecting a claim, the examiner must set forth **express findings of fact** regarding the above analysis which support the lack of written description conclusion. These findings should:

(1) Identify the claim limitation at issue; and

(2) **Establish a prima facie case by providing reasons** why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. **A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.**[3] (emphasis added)

Applicants respectfully submit that the Office's burden has not been met and that the specification provides adequate written description of the claimed invention such that one of skill in the art would recognize that Applicants' had possession of the claimed invention.

The Office has not provided "**sufficient evidence or reasoning to the contrary...to rebut the presumption**" of adequacy of the written description.[4] In fact, the Office has presented no evidence whatsoever as to why a person of skill in the art would not recognized Applicants' possession of the claimed invention. In the first Office Action, mailed December 1, 2000, the Office merely stated that not more than the specific SEQ ID NOS are adequately described and cited the above-mentioned cases in support. None of those cases establish why the skilled artisan would not recognize Applicants' possession. The Office provided no other evidence.

Then, in response to Applicants' arguments, the Office simply replies that "the rejection is maintained as being in compliance with the Office guidelines regarding written description." Again, the Office has failed to meet its burden of establishing that the invention lacks written description. A reference to "Office guidelines" is not sufficient evidence or reasoning to rebut the presumption that the invention fulfills the written description requirement.

In sum, the Office has failed to establish a *prima facie* case of lack of written description. Applicants' specification presumptively provides an adequate written description and the Office has failed to present adequate grounds to sustain a written description rejection, providing little more than conclusory statements and vague assertions. Applicants' thus submit that the presently pending claims meet the written description requirement and that this rejection of the claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

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[3] 66 Fed. Reg. 1107 (January 2001).

Nevertheless, solely in the interest of expediting prosecution, Applicants provide the following comments regarding the written description of the presently pending claims. The Office attempts to rely on the following four Federal Circuit and Board of Patent Appeals and Interferences cases in support of its assertion that the invention lacks written description.

Amgen, Inc. v. Chugai Pharmaceutical, Co.

In *Amgen, Inc. v. Chugai Pharmaceutical, Co.*, Amgen sued Genetics Institute and Chugai Pharmaceuticals for patent infringement. The Amgen patent issued on October 27, 1987 and contained claims to the DNA sequence encoding human erythropoietin (EPO). Amgen claimed priority of invention based on isolation of EPO clones in 1983.[5]

Prior to Amgen's cloning of the EPO gene, however, Genetics Institute had isolated and purified the EPO protein and had also disclosed a possible method of purifying and isolating the EPO DNA sequence.[6] The USPTO issued a patent to Genetics Institute on June 30, 1987 containing claims to the EPO protein itself.[7] Genetics Institute did not actually clone the EPO cDNA until August, 1984, and began making recombinant EPO using the cDNA shortly thereafter.[8]

The Federal Circuit held that the Amgen patent was not invalidated based on the earlier disclosure by Genetics Institute of a probing strategy to screen a DNA library for the EPO coding sequence, even though this strategy eventually resulted in the actual cloning of the gene by Genetics Institute.[9] Genetics Institute's disclosure of the protein, and a method for isolating and purifying the EPO DNA sequence, was insufficient to constitute actual conception of the DNA encoding EPO.[10] Applying chemical case law precedent,[11] the Amgen court stated:

> A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to **define it so as to distinguish it from other materials**, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the **structure of the chemical**, or is able to **define it by its method of preparation**, its physical or chemical properties, or **whatever characteristics sufficiently distinguish it**. It is not sufficient to define it solely by its principle biological property, *e.g.*, encoding human erythropoietin,

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[4] *Id.*
[5] 927 F.2d 1200 (Fed. Cir. 1991).
[6] *Id.* at 1205.
[7] *Id.* at 1203.
[8] *Id.* at 1205-06.
[9] *Id.* at 1206.
[10] *Id.*
[11] See *Oka v. Youssefyeh*, 849 F.2d 581, 583 (Fed. Cir. 1988). The court, in Amgen, classified DNA as a complex chemical compound and held that "it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and ... describe how to obtain it." *Amgen*, 927 F.2d at 1206.

> because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.[12] (emphasis added)

Thus, since Genetics Institute had not yet cloned the DNA sequence encoding EPO when it filed its patent application, and the specification only suggested a possible method by which to isolate the DNA sequence, Genetics Institute could not have a mental conception of the EPO DNA sequence at the time the application was filed.[13] The court did not invoke the requirement that the actual DNA sequence be disclosed, but only that the DNA be defined in a way to distinguish it from other chemicals along with a description of how to obtain it.[14]

Fiers v. Revel

In 1993, the Federal Circuit applied the holding in *Amgen* to an interference case where three parties (Fiers, Revel, and Sugano) claimed patent rights to the DNA encoding human fibroblast beta interferon (IFN-β). In *Fiers v. Revel*,[15] Fiers asserted priority based on his conception of a method for isolating the IFN-β DNA in 1979 or early 1980, coupled with due diligence towards a constructive reduction to practice on April 3, 1980.[16] Before he isolated the DNA, Fiers had disclosed his method to two American scientists, both of whom submitted affidavits that Fiers' method would have allowed a person of ordinary skill in the art to isolate the IFN-β DNA sequence without undue experimentation.[17]

Fiers asserted that the stringent written description requirement set forth in *Amgen* only applied when the disclosed method for isolating a DNA sequence could not easily be carried out by one of ordinary skill in the art.[18] Fiers also argued that *Amgen* allows conception of a DNA sequence by its method of isolation.[19] The Federal Circuit rejected both of these arguments, stating that Fiers was focusing inappropriately on the issue of enablement rather than written description.[20] The court also stated that, before reduction to practice, conception only of a process for making a substance, without a **conception of a structural or equivalent definition** of that substance, cannot constitute more than conception of the substance claimed as a process (product-by-process claim).[21] **Conception of a**

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[12] *Amgen*, 927 F.2d at 1206 (citations omitted).
[13] *Id.*
[14] *Id.*
[15] 984 F.2d 1164, 1166 (Fed. Cir. 1993).
[16] *Id.*
[17] *Id.*
[18] *Id.* at 1169.
[19] *Id.*
[20] *Id.*
[21] *Id.*

substance claimed *per se*, without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.[22]

Revel sought to use the benefit of a 1979 Israeli application as a constructive reduction to practice to prove priority of invention for IFN-β DNA. The court held that the Israeli application did not contain an adequate written description of a DNA encoding IFN-β because it only disclosed a method for isolating a fragment of the DNA coding for IFN-β and a method for isolating IFN-β mRNA.[23] The court concluded:

> An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself....Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for [IFN-β]. A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA.[24]

The court went on to note that the reasoning applied in *Amgen*, with respect to what is necessary to show conception, also applies to the adequacy of descriptions of DNA:

> As we stated in Amgen ... such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a **precise definition, such as by structure, formula**, chemical name, or physical properties, ... then a description also requires that degree of specificity.... [O]ne cannot describe what one has not conceived. [25]

Thus, it appears from the *Fiers* decision that there must be some specific characterization of the DNA itself to convey to one skilled in the art that the inventor was in possession of the DNA at the time of filing. The court ultimately held that Sugano, another party in the action, was entitled to priority because the disclosure in his 1980 application contained the DNA which codes for IFN-β, along with a detailed disclosure of the method used to obtain that DNA.[26]

Fiddes v. Baird

The Office also relies on the 1993 decision in *Fiddes v. Baird*,[27] in which the Board of Patent Appeals and Interferences cited *Fiers* in a priority contest over inventorship of recombinant DNA molecules encoding fibroblast growth factors ("FGFs"). Baird claimed priority on the basis of an

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[22] *Id*
[23] *Id* at 1167.
[24] *Id* at 1170-71.
[25] *Id* at 1171.
[26] *Id*.
[27] 30 USPQ2d 1398 (BPAI 1993).

application that set forth the amino acid sequence for bovine pituitary FGF and a *theoretical* DNA sequence encoding that protein, along with a method for obtaining a cDNA corresponding to the protein. The application did not teach the actual naturally-occurring DNA sequence encoding the FGF protein.[28] Since the nucleotide sequence of the naturally-occurring DNA molecule was not sufficiently disclosed, the Board followed *Fiers* in determining that Baird was not in possession of the broad class of naturally-occurring genes encoding mammalian FGFs:

> An adequate description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; **what is required is a description of the DNA itself.**
>
> * * *
>
> If a conception of a DNA requires a **specific definition, such as by structure, formula**, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity....[O]ne cannot describe what one has not conceived.[29] (emphasis added)

The Board further stated that "knowledge of the amino acid sequence of a protein coupled with the established relationship in the genetic code between a nucleic acid and the protein it encodes would not establish possession of the gene encoding that protein."[30]

Regents of the University of California v. Eli Lilly & Co.

The most recent case cited by the Office to support its assertion that the invention fails to meet the written description requirement is *Regents of the University of California v. Eli Lilly & Co.*[31] In 1977, the University of California (UC) cloned the rat insulin gene and filed a patent application that same year claiming the rat and human insulin genes, as well as broadly claiming all mammalian and vertebrate insulin genes.[32] After a patent issued to UC on the insulin gene in March 24, 1987 (U.S. Patent No. 4,652,525), UC filed suit against Eli Lilly for patent infringement for its sale of synthetic human insulin.[33] Claims 2, 4, and 5 of the '525 patent were as follows:

> 2. A recombinant procaryotic microorganism modified to contain a nucleotide sequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin.
> 4. A microorganism according to claim 2 wherein the vertebrate is a mammal.

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[28] *Id.* at 1482-81.
[29] *Id.* at 1482-83, *citing Fiers*, 984 F.2d at 1170-71.
[30] *Id.*
[31] 119 F.3d 1559 (Fed. Cir. 1997).
[32] *Id.* at 1562-63.
[33] *Id.* at 1562.

5. A microorganism according to claim 2 wherein the vertebrate is a human.

UC thus claimed all vertebrate, mammalian, and human insulin cDNA sequences.

The Federal Circuit, relying on its reasoning in *Fiers*, held that the broad claims of the '525 patent were invalid for lack of a written description.[34] The court reasoned that a description of rat insulin cDNA is not a description of vertebrate, mammalian, or human cDNA.[35] Likewise, the court reasoned that the mere name "mammalian insulin cDNA" in a claim is not an adequate description because it describes the function of the gene, but not its structure.[36] The court went on:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. **One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass**. Accordingly, **such a formula is normally an adequate description** of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus....
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or **of a recitation of structural features common to the members of the genus**, which features constitute a substantial portion of the genus...We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us...that the genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.[37] (emphasis added)

Thus, while the '525 patent specification contained adequate written description of the rat insulin cDNA, this description did not give UC a right to also claim the cDNA encoding all vertebrate or mammalian insulin. Describing one member of the genus, without reciting structural features common to the members of the genus, does not give the inventor a right to claim the entire genus, only that one member. The '525 patent provided no sequence information for the claimed human insulin cDNA.

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[34] *Id.* at 1566-69.
[35] *Id.* at 1568.
[36] *Id.* at 1568.
[37] *Id.* at 1568-69.

Simply providing a general method of producing human insulin cDNA and a description of the human insulin amino acid sequence that cDNA encodes, does not provide a written description of human insulin cDNA.[38]

The Facts of the Cited Cases are Distinct from those of the Instant Application

None of the four cases discussed above provide a situation analogous to the one at hand. In all four cases, a party was attempting to broadly claim a DNA sequence based on the amino acid sequence of the encoded protein or on the DNA sequence encoding the protein from a different animal. In no case had the party provided a sequence that was present in all members of the claimed genus of sequences or a structural characteristic common to all members of the claimed genus. As such, the party could not describe the sequence "so as to distinguish it from other materials" as required by the courts. None of the four cases are analogous to the instant application.

As stated in *Amgen*, DNA is simply a chemical compound that can be conceived of by a mental picture of the structure of the compound or whatever characteristics sufficiently distinguish it. In *Lilly*, the court stated that in claims involving chemical materials, generic formulae must indicate with specificity what the claims encompass such that one skilled in the art can **distinguish the formula from other formulas and can identify many of the species the claims encompass**. Such a formula generally constitutes an adequate written description of the claimed genus. *Lilly* also held that a **description of a genus of cDNAs may be achieved by recitation of structural features common to the members of the genus**. Moreover, the court in *Fiers* held that conception of a substance requires conception of its structure, formula, or definitive chemical or physical properties.

The Applicants of the Instant Application have Provided Nucleotide Sequences that Define the Claimed Polynucleotides

In the instant application, Applicants have provided specific nucleotide sequences that represent a distinguishing structural feature common to the genus of claimed polynucleotides. The provided sequences are the structural features that are common to the members of the claimed genus and serve to define the claimed genus. For example, claim 13 is directed to an isolated polynucleotide comprising at least 150 contiguous nucleotides of a nucleotide sequence selected from the group consisting of SEQ ID NO: 730, a degenerate variant of SEQ ID NO: 730, and a complement of SEQ ID NO: 730. With the

[38] *Id.* at 1567.

knowledge of the nucleotide sequence of SEQ ID NO: 730, one skilled in the art can easily determine if a sequence is a member of the claimed genus.

This sequence recited in the claims provides the claimed invention with a critical defining feature – one that was said to be lacking in the claims considered and rejected in each of *Amgen, Fiers, Lilly*, and *Fiddes*. The sequence recited in the claims defines the claimed polynucleotide "so as to distinguish it from other materials."[39] The recited sequence also provides "a structural or equivalent definition" of the claimed polynucleotide.[40] Moreover, the sequence recited in the claims provides "a recitation of structural features common to the members of the [claimed] genus."[41] Thus, it is much more than a mere wish to obtain a composition – it defines the composition.

The polynucleotides of the invention are also claimed in product-by-process claims, which are directed to an isolated cDNA obtained by the process of amplification using a polynucleotide comprising at least a specific number of nucleotides of a nucleotide sequence of a specific SEQ ID NO. Product-by-process claims are a well-accepted alternative way for applicants to claim their inventions.[42] These claims are in keeping with the law as expressed by the court in *Amgen*, which stated that a DNA sequence can be defined by its method of preparation.

The application also contains claims to inserts of ATCC-deposited clones. These clone inserts are fully described in the application, and they comprise a sequence of a SEQ ID NO described in the application. Accordingly, one of skill in the art would reasonably conclude that Applicants had possession of the claimed invention at the time the application was filed.

The Office has not Met It's Burden of Establishing that One Skilled in the Art would not Recognize that Applicants' had Possession of the Claimed Invention

As stated above, the Office has provided no evidence as to why one of skill in the art would not recognize Applicants' possession of the claimed invention. In the original rejection, the Office simply cited the above four cases, each of which are based upon factual scenarios inapplicable to that of the instant application. In response to Applicants' counter arguments, the Office cites PTO guidelines in upholding the rejection, again providing no evidence to support the assertion of lack of written description. Applicants fail to see how "office policy" affects the scope of a patent grantable under current case law. The courts' interpretation of 35 U.S.C. §112, first paragraph, is what determines

[39] *Amgen*, 927 F.2d at 1206.
[40] *Fiers*, 984 F.2d at 1169. *See also Fiddes*, 30 USPQ2d at 1482-83.
[41] *Lilly*, 119 F.3d at 1568-69.
[42] *See, e.g., In re Hughes*, 496 F.2d 1216 (CCPA 1974); *In re Bridgeford*, 357 F.2d 697 (CCPA 1966); Chisum §8.05.

appropriate claim scope, not "office policy." According to the above analysis of the cited cases, the pending claims fulfill the written description requirement.

Applicants also previously drew the Office's attention to U.S. Patent No. 5,861,248, which was filed on March 29, 1996, and issued on January 19, 1999. This patent discloses and broadly claims ESTs for genes that are differentially expressed in human prostate cancers as compared to normal prostate cells. As noted previously, the court decisions cited by the Office in support of the rejection were all decided prior to the granting of the '248 patent. Thus, the claims of the '248 patent were all granted by the Office in light of the same case law to which the present application is subject. While Applicants recognize that adequacy of written description is assessed on a case-by-case basis, Applicants invite the Office to explain why the written description of the '248 patent was sufficient, while that of the instant invention has been deemed insufficient, when there is no real difference between the claims or disclosure of the two inventions. Surely, a change in "office policy," under the same case law, would not account for such a difference since it is up to the courts, not the PTO, to determine the scope of the written description requirement.

Finally, in the Office's rebuttal of Applicants' response to the original rejection, the Office states that "[a]s there is no indication that the claimed SEQ ID NOS contain a complete open reading frame, the use of open language in the claims causes the claimed invention to read on at least a full open reading frame whose sequence is not described in the instant specification." Applicants are unclear as to the relevance of whether or not the claimed SEQ ID NOS contain a complete open reading frame. The claimed genus of polynucleotides are defined by a common structural characteristic such that one skilled in the art can easily determine whether a sequence falls within the claimed genus, can envision a multitude of sequences having that structural characteristic common to the claimed genus, and would thus recognize that Applicants had possession of the claimed genus at the time of filing. Nothing more is required for chemical compounds, such as nucleotide sequences.

Conclusion

The claims of the instant application are supported by an adequate written description. The Office has provided no evidence, in either the original rejection or the rebuttal of Applicants' response, to establish that one of skill in the art would not recognize that Applicants had possession of the claimed invention at the time the application was filed. The four cases cited in support of the Office's assertions in the original rejection did not address a situation similar to the one at hand, where common structural features have been provided for all members of the claimed genera.

As stated above, the claimed genera of polynucleotides are defined by common structural characteristics such that one skilled in the art can easily determine whether a sequence falls within a claimed genera, can envision a multitude of sequences having that structural characteristic common to a claimed genera, and would thus recognize that Applicants had possession of the claimed genera at the time of filing. Moreover, as noted above, the Office has failed to provide the "sufficient evidence or reasoning" necessary to support a written description rejection. Conclusory statements can not, standing alone, constitute a *prima facie* case of lack of written description. Accordingly, Applicants respectfully request withdrawal of this rejection of claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-122 under 35 U.S.C. §112, first paragraph.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number 23001487.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

New claims 123-133 have been added.